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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 07/25/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/847,134

Applicant(s)

HOFFMAN ET AL.

Examiner

D. L. Jones

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2001 and 28 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 & 6. 6) ☐ Other: _____.

APPLICANT'S INVENTION

1. Applicant's invention is directed compounds and uses thereof comprising a metal, chelating group, and a bombesin agonist.

STATUTORY DOUBLE PATENTING

2. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

3. Claims 1, 2, and 14 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 5, and 6 of copending Application No. 10/122,611. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

4. Claims 1 and 46 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 7 of prior U.S. Patent No. 6,200,546. This is a double patenting rejection.

OBVIOUSNESS-TYPE DOUBLE PATENTING

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 3-9, 11, 12, 15-22, 33, 34, and 37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable

over claims 7-10, 16-26, 57, and 58 of copending Application No. 10/122,611. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant invention differ from those of 10/122,611 in that specific species are disclosed for some of the variables, for example the variable Y.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claim 37 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,200,546. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim of the instant invention encompasses that of the patented invention. In particular, the claims of the instant invention are not limited to the treatment of a specific condition as in the patented claims.

112 REJECTIONS

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-61: The claims as written are ambiguous because the claims appear to be somewhat inconsistent with what is disclosed in the specification. In particular, the claims as written require a metal, chelating group, and a gastrin releasing peptide which includes a bombesin agonist-binding moiety. Thus, it appears as if the claims require four components, a metal, chelating group, gastrin, and bombesin agonist. However, the summary and detailed description of the invention disclose that one embodiment of the instant invention is a compound comprising a metal, chelating group, and gastrin (pages 3-4, bridging paragraph; page 6, lines 1-5). Furthermore, Figure 1 which is discussed in the detailed description of the invention discloses a chelator, spacer group, and bombesin binding region. Hence, Applicant is respectfully requested to clarify the claims in order that one may readily ascertain what is being claimed.

Claims 4, 6, 11, 17, 19, 33, 41, 42, 49, 50, 58, 60, and 61: The claims as written are ambiguous because of the phrase 'derivatives thereof'. In particular, the claims are ambiguous because one cannot readily ascertain which portion(s) of the parent compounds are retained in the derivatives or exactly what compound(s) is/are encompassed by Applicant's definition. It is respectfully suggested that Applicant delete the phrase.

103 REJECTIONS

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-7, 11, 12, 14-20, 33, 34, 37-43, 46-51, and 53-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albert et al (US Patent No. 5,686,410) in view of Edwards et al (US Patent No. 5,428,019), and in further view of Srinivasan et al (US Patent No. 4,988,496).

Albert et al disclose a biologically active peptide (e.g., bombesin) bearing at least one chelating group and a detectable label. The complex is useful as a radiopharmaceutical for in vivo imaging of target tissues or for therapy (see entire document, especially, abstract; column 2, lines 3-25). In addition, Albert et al disclose (a) the chelating group may be attached directly or indirectly to the peptide (column 1, lines 47-53; column 3, lines 20-32). (b) Various possible chelators that may be attached to the peptide include DTPA, DOTA, and nitrogen-sulfur containing groups, among several other groups (column 3, lines 47-68; and column 5, lines 3-55). (c) Various detectable elements such as heavy elements or rare earth ions or other elements may be conjugated to the complex (column 12, lines 56-68; and column 13, lines 1-29). Albert et al fail to specifically state that the bombesin peptide may be an agonist and other possible chelating groups which may be conjugated to the peptide.

Edwards et al disclose bombesin analogs (agonists and antagonists) that may be used in the treatment of various disorders (see entire document, especially, abstract; column 3, lines 57-68; column 15, lines 47-68). The bombesin analogs may act as agonist or antagonist (column 14, lines 37-45).

Srinivasan et al disclose metal radionuclide chelating compounds. In particular, Srinivasan et al disclose that targeting agents such as bombesin may be conjugated to various chelators such as N2S3, N2S4, or N3S3 chelators (see entire document, especially, abstract; column 7, lines 65-66; column 6, lines 58-60; and column 14, lines 36-49).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Albert et al using the teachings of Edwards et al and Srinivasan et al and generate a compound and uses thereof comprising a metal, chelator, and bombesin agonist because (1) Albert et al disclose a biologically active peptide (e.g., bombesin) may bear at least one chelator, and a detectable label. (2) Edwards et al disclose that bombesin agonists are known in the art and useful for treatment of various disorders. (3) Srinivasan et al disclose that it is known in the art to conjugate targeting agents (e.g., bombesin) to various pharmaceutically acceptable chelators (e.g., N2S2, N2S4, N3S3, etc).

Furthermore, since each of the reference is directed to bombesin, the references may be considered to be within the same field of endeavor. Thus, the references are combinable.

SPECIFICATION

12. The disclosure is objected to because of the following informalities: some of the bonds on page 14, line 6, are unreadable. Likewise, the data on pages 43-45 is unreadable. Thus, Applicant is respectfully requested to submit clean copies.

Appropriate correction is required.


COMMENTS/NOTES

13. It is duly noted that the supplemental information disclosure statement filed 1/28/02 contained a few duplicate copies of documents filed 8/30/01. However, the lined through document without the term 'Duplicate' next to it was not present in the application during examination.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose' Dees can be reached on (703) 308- 4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


D. L. Jones
Primary Examiner
Art Unit 1616

July 17, 2002